IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN, INC.,	§	
	§	
Plaintiff,	§	
	§	
v.	§	Case No. 2:15-cv-1455-WCB
	§	LEAD CASE
TEVA PHARMACEUTICALS USA, INC., et al.,	§	
	§	
	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

Before the Court is Defendants' Motion for Leave to Amend Invalidity Contentions ("Motion to Amend"), Dkt. No. 303. The Motion to Amend is GRANTED, and the parties are directed to meet and confer regarding appropriate fact discovery related to the subject matter of the motion, as discussed below.

BACKGROUND

The defendant pharmaceutical companies are seeking approval by the Food and Drug Administration to sell a generic version of Restasis, an ophthalmic product sold by plaintiff Allergan, Inc. On August 24, 2015, Allergan filed a patent infringement action under the Hatch-Waxman Act against defendants Teva Pharmaceuticals USA, Inc.; Akorn, Inc.; Mylan Pharmaceuticals, Inc.; and Mylan, Inc., alleging infringement of several Allergan patents related to Restasis. Allergan, Inc. v. Teva Pharmaceuticals USA, Inc., No. 2:15-cv-1455 (E.D. Tex.). Allergan later filed related actions against defendants Innopharma, Inc., and Famy Care Limited. Allergan, Inc. v. Innopharma, Inc., No. 2:15-cv-1504 (E.D. Tex., filed Sept. 8, 2015); Allergan, Inc. v. Famy Care Ltd., No. 2:16-cv-401 (E.D. Tex., filed April 12, 2016). The latter two actions were consolidated with case no. 2:15-cv-1455.

The defendants asserted anticipation and obviousness defenses based on two patents issued to Dr. Shulin Ding, who worked for Allergan as a formulator from 1987 to 1998. See Dkt. No. 303-2, at 9. During the discovery period, Allergan turned over documents related to Dr. Ding's work on cyclosporin treatments. In March 2016, Allergan produced Dr. Ding's 1997 Technical Report entitled "Technology Transfer Report for Phase III Manufacture of Cyclosporine 0.1% and 0.05% Ophthalmic Emulsions," as well as a draft technical report entitled "Freeze to Thaw and Low to High Cycling Studies Report for Cyclosporine Ophthalmic Emulsion Formulations 8735X and 9054X." See Dkt. No. 315-1. In September 2016, Allergan produced the laboratory notebook of Toan Ha, who worked under Dr. Ding. See Dkt. No. 315-2.

In January 2017, the defendants deposed several witnesses regarding Dr. Ding's involvement in Allergan's development of Restasis. See, e.g., Dkt. No. 314-2, at 33, 51. On January 16, 2017, the defendants noticed Dr. Ding's deposition and served a subpoena for the production of documents related to her work on the development of Restasis. See Dkt. No. 314, at 4.

Fact discovery closed on February 10, 2017. See Dkt. No. 269, at 2. The defendants deposed Dr. Ding on February 24, 2017, as she had not been available before then, see Dkt. No. 314, at 4. Additional materials were produced to the defendants the day before her deposition, including a copy of the previously produced draft technical report, but with Dr. Ding's handwritten notes on it. Dkt. No. 303, at 6-7.

On March 20, 2017, the defendants notified Allergan that they intended to seek leave to add a new invalidity theory of incorrect inventorship under 35 U.S.C. § 102(f). Allergan opposed the amendment. See Dkt. No. 314, at 4.

The deadline for the parties to amend their pleadings was June 9, 2016. Dkt. No. 137, at 3.[1] The defendants filed their Motion to Amend on March 24, 2017.

DISCUSSION

Once a scheduling order has been entered in a case and a deadline has been set for filing amended pleadings, the decision whether to permit a post-deadline amendment is governed by Fed. R. Civ. P. 16(b). See Squyres v. Heico Companies, L.L.C., 782 F.3d 224, 237 (5th Cir. 2015); EEOC v. Serv. Temps Inc., 679 F.3d 323, 333-34 (5th Cir. 2012); L.G. Motorsports, Inc. v. NGMCO, Inc., No. 4:11-cv-112, 2013 WL 2543398, at *6 (E.D. Tex. June 6, 2013). Under Rule 16(b)(4), a motion to modify the scheduling order by permitting the filing of an amended pleading after the deadline in the scheduling order may be granted "only for good cause and with the judge's consent."

The party seeking to modify a scheduling order has the burden to show good cause. Squyres, 782 F.3d at 237; Self v. Quinn's Rental Servs. (USA), LLC, Civil Action No. H-15-1569, 2016 WL 6835093, at *1 (S.D. Tex. Nov. 21, 2016). Moreover, the Fifth Circuit has held that Rule 16 gives trial courts "broad discretion to preserve the integrity and purpose of the pretrial order." Geiserman v. MacDonald, 893 F.2d 787, 790 (5th Cir. 1990) (quoting Hodges v. United States, 597 F.2d 1014, 1018 (5th Cir. 1979)). The Fifth Circuit has directed that in deciding whether to permit amendments to the pleadings after the deadline for such amendments, district courts should consider "(1) the explanation for the party's failure to [timely move for leave to amend]; (2) the importance of the [amendment]; (3) potential prejudice in allowing the [amendment]; and (4) the availability of a continuance to cure such prejudice." United States ex rel. Bias v. Tangipahoa Parish Sch. Bd., 816 F.3d 315, 328 (5th Cir. 2016) (quoting S&W

[1] For Famy Care Ltd., the deadline was August 31, 2016. See Dkt. No. 170, at 3.

Enters., L.L.C. v. SouthTrust Bank of Ala., N.A., 315 F.3d 533, 536 (5th Cir. 2003) (alterations in original)); Filgueira v. U.S. Bank Nat'l Ass'n, 734 F.3d 420, 422 (5th Cir. 2013); Ciena Corp. v. Nortel Networks, Inc., 233 F.R.D. 493, 494 (E.D. Tex. 2006). The Court will consider each of those factors in exercising its discretion whether to grant the Motion to Amend.

I. The Defendants' Explanation for the Untimely Motion to Amend

The defendants contend that they did not have a sufficient basis to assert an invalidity defense based on the nonjoinder of an inventor under 35 U.S.C. § 102(f) until they deposed Dr. Ding. The defendants also point out that they noticed Dr. Ding's deposition before the close of fact discovery, but that the deposition was postponed to accommodate Dr. Ding's retirement schedule.

In response, Allergan argues that the defendants had all the necessary material to raise a 102(f) invalidity defense by at least September 2016, and that Dr. Ding's testimony merely "confirmed" what was apparent from that material. Allergan also notes that after Dr. Ding's deposition, the defendants waited a month before filing the Motion to Amend and that they offer no explanation for that period of delay.

The Court finds that the defendants are not at fault for the delay between the time of Allergan's early production of materials regarding Dr. Ding's work and the time of Dr. Ding's deposition. The materials produced earlier show that (1) Toan Ha set forth the Restasis formulation and that formulation was in fact manufactured for further study with Dr. Ding's approval, Dkt. No. 303-7; (2) Dr. Ding authored the 1997 Technical Report which stated that a cyclosporin product was selected for Phase III studies, Dkt. No. 303-8; and (3) studies conducted on 0.1% and 0.05% cyclosporin emulsions showed that the two emulsions performed similarly, see Dkt. No. 303-9, at 4.

Those earlier materials suggest that Dr. Ding played a role in the development of cyclosporin treatments generally.[2] Her deposition testimony, however, went farther, showing that she may have played a significant role in the development of the specific formulation for Restasis.

During her deposition, Dr. Ding testified that in 1993 or 1994 she began working on the development of Restasis and that she continued working on that project until she left Allergan in 1998. See Dkt. No. 303-2, at 11, 14, 16. She stated that she conducted experiments with the specific formulation for Restasis. Id. at 99, 101. When shown the laboratory notebook of Toan Ha, which discloses that formulation, Dr. Ding testified that Toan Ha was a staff member working under her guidance. Id. at 93-94.

Also at her deposition, Dr. Ding confirmed that she was the author of the 1997 Technical Report. Dkt. No. 303-2, at 143-44. More importantly, she explained that the product moving into Phase III study, identified in the Technical Report as "9054X," is the same as the Restasis formulation disclosed in Toan Ha's laboratory notebook, where the formulation is identified as "9054."

Finally, Dr. Ding testified regarding the recently produced handwritten notes on the draft technical report. Dkt. No. 303-2, at 172. She stated that she had written the handwritten note that read: "The two formulations [0.1% and 0.05%] are similar in every regard with the exception of cyclosporine concentration." She then explained that the note refers to the

[2] The Court does not include deposition testimony from other witnesses regarding Dr. Ding's role as "earlier material" that may have prompted the defendants to seek to amend their invalidity contentions at an earlier time. Allergan points to relevant deposition testimony from Dr. Brenda Reis on January 13, 2017, see Dkt. No. 314, at 3-4, but the defendants promptly noticed Dr. Ding's deposition three days later on January 16, 2017.

formulations in Toan Ha's laboratory notebook, including the 0.05% Restasis formulation, 9054.[3]

In sum, the early production may have prompted the defendants to question Dr. Ding's role regarding the invention, but it was Dr. Ding's later deposition testimony that enabled the defendants to conclude that Dr. Ding in fact conducted studies on the Restasis formulation and that she "came up with the formulations for Phase [III]" testing. Dkt. No. 303-2, at 93-94. The defendants could reasonably have believed that the additional evidence of Dr. Ding's testimony provided a good faith basis to assert a defense that requires "clear and convincing, corroborated evidence." Winbond Elecs. Corp. v. Int'l Trade Comm'n, 262 F.3d 1363, 1371 (Fed. Cir. 2001).

While the Court finds that the defendants were not at fault for failing to seek leave to amend their invalidity contentions prior to Dr. Ding's deposition, the Court finds that the defendants were not diligent in filing the Motion to Amend after deposing Dr. Ding. The defendants are therefore at fault for the one-month period of delay between Dr. Ding's deposition and the defendants' filing of the Motion to Amend.

In general, this factor cuts in favor of allowing the amendment, but the defendants are somewhat at fault for not filing the Motion to Amend more promptly after the deposition of Dr. Ding.

II. The Importance of the Amendment

The defendants argue that the proposed amendment is important because, "if successful, the defense would dispose of all of Allergan's claims." Dkt. No. 303, at 10. What the defendants fail to acknowledge, however, is that the defense, if successful, would *temporarily*

[3] Allergan states that this handwritten note was incorporated in the version produced to the defendants in September 2016. Dkt. No. 314, at 7 & n.3. In that earlier produced version, however, it was not apparent that the note was a proposed edit attributable to a particular individual.

dispose of all of Allergan's claims, but would not necessarily dispose of those claims *permanently*. As explained in detail in Cassidian Communications, Inc. v. Microdata, GIS, Inc., No. 2:12-CV-162, 2015 WL 1848533 (E.D. Tex. Apr. 20, 2015), a successful defense based on a finding of incorrect inventorship is not necessarily a win for the defendants. Allergan may invoke (and has, in the alternative, already invoked, see Dkt. No. 319, at 4-5) the correction of inventorship statute, 35 U.S.C. § 256, "to save the patent from invalidity" in the event the defendants succeed in their section 102(f) defense. Pannu v. Iolab Corp., 155 F.3d 1344, 1350 (Fed. Cir. 1998); see also Winbond Elecs. Corp. v. Int'l Trade Comm'n, 262 F.3d 1363, 1371 (Fed. Cir. 2001) ("Incorrect inventorship is a technical defect in a patent that may be easily curable."). As occurred in the Cassidian Communications case, the defendants could win on their inventorship defense, but Allergan could move to correct inventorship under section 256 and, if prevailing on that motion, move to vacate the judgment of invalidity. No. 2:12-CV-162, 2015 WL 1848533, at *4. Significantly, "the correction of inventorship does not affect the validity or enforceability of the patent for the period before the correction." Viskase Corp. v. Am. Nat'l Can Co., 261 F.3d 1316, 1329 (Fed. Cir. 2001). So, the defendants could prove incorrect inventorship but still be liable for infringement following an order correcting the error in the naming of inventors.

That is not to say that an amendment raising such a defense is invariably futile and therefore must be regarded as unimportant. For example, the defendants' success would not be futile in the event Allergan failed to seek, or obtain, correction of inventorship. See Stark v. Advanced Magnetics, Inc., 119 F.3d 1551, 1554-55 (Fed. Cir. 1997). In addition, to allow potential futility in this context to preemptively defeat any incorrect inventorship defense would

not only deprive any defendant entirely of that defense, but it also would deprive the public of the significant benefit of correcting the inventorship on an issued patent.

The law provides different incentives to name the correct inventors, whether by imposing a duty to disclose such information on those individuals associated with the filing and prosecution of patent, see 37 C.F.R. § 1.56; allowing for the correction of inventorship during the application process, 35 U.S.C. § 116; allowing for the correction of inventorship on an issued patent, 35 U.S.C. § 256; or allowing a defendant to assert an invalidity defense on that basis during litigation, see 35 U.S.C. § 102(f). The Court will not bar the defendants from asserting their rights under section 102(f) simply because Allergan has the potential for correcting inventorship under section 256 and thereby avoiding invalidation of its asserted patents.

In determining the importance of the amendment, the Court must make a pragmatic judgment as to the likelihood that the newly asserted defense will succeed. See Filgueira, 734 F.3d at 423 ("Filgueira fails to show the importance of his amendment" because "it would not have changed the outcome of the court's ruling" on the motion to dismiss.); Sw. Bell Tel. Co. v. City of El Paso, 346 F.3d 541, 547 (5th Cir. 2003) (treating "likely failure of the proposed counterclaims on the merits" as a factor weighing against allowing untimely amendment); see also Bombardier Aerospace Corp. v. United States, 831 F.3d 268, 284 (5th Cir. 2016) (futility of amendment supports decision to deny motion to amend); Tangipahoa Parish Sch. Bd., 816 F.3d at 328 (same); Nourison Rug Corp. v. Parvisian, 535 F.3d 295, 299 (4th Cir. 2008) (same). Based on Dr. Ding's deposition testimony and the supporting materials, it appears that the defendants have some likelihood of success in showing that Dr. Ding was a co-inventor. Because the defendants' effort to invalidate the patent on those grounds is not necessarily futile,

the Court regards the amendment as being of sufficient importance to justify overlooking the defendants' failure to meet the deadline for amending their invalidity contentions.

III. Prejudice to Allergan

The defendants claim the amendment to the invalidity contentions would not prejudice Allergan because Allergan "has the relevant documents" to respond to the defense and "still employs or otherwise controls ten 'Allergan witnesses [] all of whom had knowledge of the Restasis development.'" Dkt. No. 317, at 4 (quoting Dkt. No. 314, at 7). Allergan, however, responds that several key witnesses are not employed by Allergan, and that Allergan would need further fact discovery in an already compressed schedule in order to diligently respond to the proposed amendment. See Dkt. No. 319, at 4.

Although most of the relevant information is likely in Allergan's possession, the Court agrees that an amendment would burden Allergan to the extent that Allergan would need to conduct further fact discovery from third-party witnesses. However, any potential prejudice resulting from the need to conduct limited additional discovery can be cured by reopening fact discovery for the limited purpose of allowing Allergan to investigate the inventorship issue, and by allowing Allergan to assert a conditional claim for correction of inventorship under 35 U.S.C. § 256. The prejudice factor therefore cuts in favor of the defendants.

IV. The Availability of a Continuance

The Court agrees with Allergan that a continuance may "erode Allergan's 30-month stay," Dkt. No. 314, at 9, but the Court also agrees with the defendants that no continuance is warranted. Most of the relevant information pertaining to the inventorship issue is already in Allergan's possession, and there is sufficient time for Allergan to conduct the limited fact discovery before the filing of dispositive and Daubert motions, and certainly before trial. The

"availability of a continuance" factor is therefore not relevant to the Court's decision on the defendants' motion.

Upon weighing the factors that bear on whether to grant the Motion to Amend, the Court concludes that none of those factors favors Allergan and that the interest of justice favors allowing the defendants to amend their invalidity contentions. Accordingly, the Motion to Amend is GRANTED.

The parties are directed to promptly meet and confer regarding the discovery needed by Allergan to oppose the inventorship defense. The Court expects that the parties will be able to reach agreement on that issue. However, in the event of a dispute, the Court orders that the parties present the dispute to the Court no later than May 5, 2017.

IT IS SO ORDERED.

SIGNED this 27th day of April, 2017.

William C. Bryson

WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE